Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

#### **Toxicology Data Management System**

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical			
Male										
Southern Research Institute	059903705	06/09/03	729	50(3)	27(662)	523.0	alpha/beta Thujone mixture			
					Female					
Southern Research Institute	059903705	06/09/03	730	50(5)	35(689)	335.4	alpha/beta Thujone mixture			

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

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			Male			Female			
#All Organs: Benign Tumors									
		44/50 (88%)				46/50 (92%)			
Overall Incidence	Total	44/50 (88%)	Mean 88%	SD 0%	Total	46/50 (92%)	Mean 92%	SD 0%	
#All Organs: Malignant Tumors									
		31/50 (62%)				20/50 (40%)			
Overall Incidence	Total	31/50 (62%)	Mean 62%	SD 0%	Total	20/50 (40%)	Mean 40%	SD 0%	
#All Organs: Malignant and Benign T	umors								
		48/50 (96%)				49/50 (98%)			
Overall Incidence	Total	48/50 (96%)	Mean 96%	SD 0%	Total	49/50 (98%)	Mean 98%	SD 0%	
#All Organs: Hemangioma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma or H	emangioma								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 39

			Male				Female			
#All Organs: Histiocytic Sarcoma										
		1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs:										
Leukemia: Lymphocytic	c, Monocytic, Mo	ononuclear, or Undifferen	ntiated			(0.00)				
		22/50 (44%)				10/50 (20%)				
Overall Incidence	Total	22/50 (44%)	Mean 44%	SD 0%	Total	10/50 (20%)	Mean 20%	SD 0%		
#All Organs:										
•	Histiocytic, Lym	phocytic, Mixed, NOS, or	Undifferentiated Ce	ell Type						
		0/50 (0%)		• •		1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#All Organs:			•••••							
#All Organs:						0/50 (0%)				
#All Organs:			Mean 4%	SD 0%	Total		Mean 0%	SD 0%		
#All Organs: Mesothelioma: Benign,	Malignant, NOS	2/50 (4%)				0/50 (0%)				
#All Organs: Mesothelioma: Benign, Overall Incidence	Malignant, NOS	2/50 (4%)				0/50 (0%)				
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs:	Malignant, NOS	2/50 (4%)				0/50 (0%)				
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs:	Malignant, NOS	2/50 (4%) 2/50 (4%)				0/50 (0%) 0/50 (0%)				
#All Organs: Mesothelioma: Benign, Overall Incidence  #All Organs: Mesothelioma: Maligna Overall Incidence  #All Organs:	Malignant, NOS  Total  nt	2/50 (4%) 2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Mesothelioma: Benign, Overall Incidence  #All Organs: Mesothelioma: Maligna Overall Incidence	Malignant, NOS  Total  nt	2/50 (4%) 2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

#All Organs: Osteosarcoma

#All Organs:

**Overall Incidence** 

**Overall Incidence** 

\*Adrenal Cortex: Adenoma

**Overall Incidence** 

\*Adrenal Cortex: Carcinoma

**Overall Incidence** 

\*Adrenal Medulla:

**Overall Incidence** 

**Overall Incidence** 

\*Adrenal Medulla:

.....

Osteosarcoma or Osteoma

.....

Pheochromocytoma Benign

**Pheochromocytoma Complex** 

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Male **Female** 1/50 (2%)1/50 (2%)1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% 1/50 (2%)1/50 (2%)1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% 1/50 (2%)1/47 (2%)1/50 (2%) Mean 2% SD 0% Total 1/47 (2.13%) Mean 2.13% SD 0% 0/50 (0%)0/47 (0%)0/50 (0%) Mean 0% SD 0% Total 0/47 (0%) Mean 0% SD 0% 6/50 (12%)2/48 (4%)6/50 (12%) Mean 12% SD 0% Total 2/48 (4.17%) Mean 4.17% SD 0%

1/48

Total

1/48 (2.08%)

(2%)

Mean 2.08%

SD 0%

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Report Date: 06/05/2013

Total

Total

Total

Total

Total

Total

0/50

0/50 (0%)

(0%)

Mean 0%

SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: F 344/N

**Toxicology Data Management System** 

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Mean 2%

SD 0%

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: RATS

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRON	NIC											
			Male			Female						
*Adrenal Medulla: Pheochromocytoma Malignant												
•	· ·	0/50 (0%)				0/48 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma: E	Benign, Complex,	, <b>Malignant, NOS</b> 6/50 (12%)				3/48 (6%)						
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	3/48 (6.25%)	Mean 6.25%	SD 0%				
#Blood Vessel: Leiomyosarcoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Bone: Chordoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Bone: Osteoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Bone: Osteosarcoma		1/50 (2%)				1/50 (2%)						

SD 0%

1/50 (2%)

Total

Total

1/50 (2%)

Mean 2%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Bone: Osteosarcoma or Osteoma								
		1/50 (2%	b)			1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Brain: Glioma								
		0/50 (0%	5)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Glioma Benign		0/50 (00/	`			0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		, ,				, ,		
*Brain: Glioma Malignant		0/50 (00/	,			4/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Brain: Oligodendroglioma, Glioma,								
	•	0/50 (0%	o)			1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Brain: Osteosarcoma								
		0/50 (0%	,			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Clitoral/Preputial Gland: Adenoma								
		2/49 (4%)				12/50 (24%)		
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%	Total	12/50 (24%)	Mean 24%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
		1/49 (2%)				2/50 (4%)		
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		2/40 /69/\				44/50 (200/)		
Overall Incidence	Total	3/49 (6%) 3/49 (6.12%)	Mean 6.12%	SD 0%	Total	14/50 (28%) 14/50 (28%)	Mean 28%	SD 0%
		, ,						
*Clitoral/Preputial Gland: Sarcoma		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor	•••••							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Benign		0/50 /02/				0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan OO/	CD 00/
Overali incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Eye: Melanoma Malignant								
-		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma								
		0/50 (0%)		05.00/		0/50 (0%)		05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma								
		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	05.00/		0/50 (0%)		05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign								
		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Large: Colon/Rectu Adenoma	m:							
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Intestine Large: Colon/Rectu Carcinoma or Adenoma						4/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Intestine Small: Duodenum: Leiomyoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma		0/50 /00/				0/50 (00/)		
Overall Insidence	Tatal	0/50 (0%)	Mann 00/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Mean 0%

SD 0%

Report Date: 06/05/2013

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Jejunum: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% ..... #Intestine Small: Site Unspecified: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Leiomyoma 0/50 (0%)0/50 (0%)

SD 0%

Total

0/50 (0%)

Total

0/50 (0%)

Mean 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N Length of Study: CHRONIC

Leiomyosarcoma

**Overall Incidence** 

**Overall Incidence** 

\*Islets, Pancreatic: Adenoma

**Overall Incidence** 

\*Islets, Pancreatic: Carcinoma

**Overall Incidence** 

\*Islets, Pancreatic:

#Intestine Small: Site Unspecified:

#Intestine Small: Site Unspecified: Schwannoma Malignant

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Male **Female** 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 1/49 (2%)Mean 2% SD 0% Total 1/49 (2.04%) Mean 2.04% SD 0% 0/49 (0%)

0/49 (0%)

Total

Page: 47

Mean 0%

SD 0%

Report Date: 06/05/2013

Carcinoma	or	Adenoma	

.....

3/50 (6%) 1/49 (2%)

Overall Incidence Total 3/50 (6%) Mean 6% SD 0% Total 1/49 (2.04%)

Mean 4%

0/50

0/50 (0%)

0/50

0/50 (0%)

1/50

1/50 (2%)

2/50

2/50 (4%)

Total

Total

Total

Total

\*: Denominator is number of animals with tissues examined microscopically

(0%)

(0%)

(2%)

(4%)

 Overall Incidence
 Total
 3/50 (6%)
 Mean 6%
 SD 0%
 Total
 1/49 (2.04%)
 Mean 2.04%
 SD 0%

# \*Kidney: Pelvis and Transitional Epithelium:

Papilloma

0/48 (0%) 0/48 (0%) Mean 0% SD 0% Total 0/44 (0%)

SD 0%

 Overall Incidence
 Total
 0/48 (0%)
 Mean 0%
 SD 0%
 Total
 0/44 (0%)
 Mean 0%
 SD 0%

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		0/48 (0%)				0/44 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/44 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/44 (0%) 0/44 (0%)	Mean 0%	SD 0%
					ı Olai			
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/48 (0%)				0/44 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/44 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma		0/48 (0%)				0/44 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/44 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Malig								
		0/48 (0%)				1/44 (2%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	1/44 (2.27%)	Mean 2.27%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
		0/48 (0%)		05.00/		0/44 (0%)		05 00/
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/44 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: METHYLCELLULOSE Report Date: 06/05/2013

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				Mal	e			Female	
*Liver: Hepatocellular Adenoma	ı	,							
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
	ı olal	0/50 (0%)		iviean 0%	3D 0%		0/50 (0%)	wiean 0%	טע ט%
*Liver: Hepatocellular Carcinom	ıa								
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinom	a or Hepatobla		(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinom		lular Adenoma	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinom		ar Adenoma, or					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0,0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Benign		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	(= /0)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 50

Report Date: 06/05/2013

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female		
*Lung: Alveolar/Bronchiolar A	Adenoma								
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Lung: Alveolar/Bronchiolar C									
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
		eolar/Bronchiolar Adenor 2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Lung: Fibrosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenolipoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenoma									
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

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			Male				Female	
#Mammary Gland: Carcinoma								
		0/50 (0%	)			2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%	)			3/50 (6%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
#Mammary Gland: Fibroadenoma								
O	T-1-1	3/50 (6%	,	OD 00/	T-1-1	26/50 (52%)	Maria 500/	00 00/
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	26/50 (52%)	Mean 52%	SD 0%
Mammary Gland: Fibroma								
Overall Incidence	Total	0/50 (0% 0/50 (0%)	) Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
		` ,				` '		
#Mammary Gland: Fibroma, Fibroadenoma or	Adenoma							
		3/50 (6%	)			28/50 (56%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	28/50 (56%)	Mean 56%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, Ca		Adenoma						
Overell lesidence	Tatal	3/50 (6%	,	CD 00/	Tatal	30/50 (60%)	Mana C00/	CD 00/
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	30/50 (60%)	Mean 60%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

# **Toxicology Data Management System**

Contract/Lab: All Laboratories Tumor Incidence for

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 52

			Male				Female	
#Mesentery: Fibrous Histiocytoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Schwannoma Malignan	nt							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Nose: Adenoma								
O	T-1-1	0/50 (0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	00.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o		nx, Tooth, Gingiva):						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phary							
•		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phary					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 53

			Male				Female	
#Oral Mucosa: Squamous Cell Carcinoma	1							
·		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Papilloma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma						0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Fibrosarcoma Overall Incidence					Tatal	0/50 (0%)	M 00/	CD ov
					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Ber	nign					0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Mal	ignant							
						1/50 (2%)		05 00/
Overall Incidence					Total	1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: F 344/N

**Toxicology Data Management System** 

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(0%)

Mean 0%

0/49

0/49 (0%)

Total

Report Date: 06/05/2013

SD 0%

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: GAVAGE

Vehicle: METHYLCELLULOSE

	Male			Female  Mean 2% SD 0%  Mean 0% SD 0%			
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS							
			1/50 (2%)				
Overall Incidence		Total	1/50 (2%)				
*Ovary:							
Granulosa-Theca Tumor Malignant			- / / / / / / / / / /				
Occupation of the second		T-1-1	0/50 (0%)	M 00/	00.00/		
Overall Incidence		Total	0/50 (0%)				
Ovary:							
Schwannoma Malignant							
• " "		<b>.</b>	0/50 (0%)		00.00/		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%		
Ovary: Sertoli Cell Tumor Malignant							
Serion Gen Tumor manghant			0/50 (0%)				
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%		
				•••••			
Ovary: Tubulostromal Adenoma							
i ubulostromai Adenoma			0/50 (0%)				
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%		
*Pancreas:							
Adenoma							

SD 0%

Total

(0%)

Mean 0%

0/50

0/50 (0%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 55

			Male				Female	
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Benign								
		1/50 (2%)				0/49 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma		0/40 (00/)				0/47 (00/)		
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
Overall incidence		, ,				, ,		
*Pituitary Gland: Pars Distal Adenoma	is or Unspeci	fied Site:						
		24/50 (48%)				25/50 (50%)		
Overall Incidence	Total	24/50 (48%)	Mean 48%	SD 0%	Total	25/50 (50%)	Mean 50%	SD 0%
*Pituitary Gland: Pars Distal Carcinoma			•••••					
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Pituitary Gland: Pars Distal Carcinoma or Adenoma		fied Site:						
		24/50 (48%)				26/50 (52%)		
Overall Incidence	Total	24/50 (48%)	Mean 48%	SD 0%	Total	26/50 (52%)	Mean 52%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Species:** RATS **Strain:** F 344/N

Length of Study: CHRONIC

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			Male				Female		
*Pituitary Gland: Pars Distal Ganglioneuroma	lis or Unspeci	fied Site:							
J		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Pituitary Gland: Pars Intern Adenoma									
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Pituitary Gland: Pars Intern Carcinoma or Adenoma									
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Pituitary Gland: Pars Nervo Craniopharyngioma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Prostate: Adenoma									
		2/50 (4%)							
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%					
*Prostate: Carcinoma or Adenoma		2/50 (4%)							
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%					
Jveran illelueliee	illai	2/30 (4/0)	IVICALI 4/0	3D 0/0					

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 57

Report Date: 06/05/2013

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female           Total         0/50 (0%)         Mean 0%         SD 0%           Total         0/50 (0%)         Mean 0%         SD 0%		
*Salivary Glands: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma		0(50 (00))				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	( ,	Mean 0%	SD 0%
*Salivary Glands: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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				Male				Female	
#Skeletal Muscle: Lipoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma									
		1/50	(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Adenoma or E	Basosquamous	Tumor Benign 1/50	(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Adenoma, Bas		ımor Benign, oı					1/50 (2%)		
Overall Incidence	Total	3/50 (6%)	, ,	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Carcinoma									
		1/50	(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Carcinoma or	Basosquamou	s Tumor (malig					1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

**Page:** 59

			Male				Female					
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tui	mor (benign, maligna	nt or								
		4/50 (8%)				2/50 (4%)						
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%				
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 9/50 (18%) 2/50 (4%) Overall Incidence Total 9/50 (18%) SD 0% Total 9/50 (18%) SD 0% Total 9/50 (18%) SD 0%												
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%				
#Skin: Fibroma		11/50 (22%)				2/50 (4%)						
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%				
#Skin: Fibroma, Fibrosarcoma Overall Incidence	a, Sarcoma, Myxo	oma, Myxosarcoma, or F 16/50 (32%) 16/50 (32%)	ibrous Histiocytoma  Mean 32%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%				
#Skin: Fibrosarcoma		3/50 (6%)				0/50 (0%)						
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Fibrosarcoma, Sarcom	a, Myxosarcoma	, or Fibrous Histiocytom 6/50 (12%)	a			0/50 (0%)						
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 60

			Male				Female	
#Skin: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma								
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor		0(50 (00))				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

**Page:** 61

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			Female				
#Skin: Neurofibroma or Schwan	noma benign									
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin:										
Neurofibrosarcoma or Sc	hwannoma (m	0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Neurofibrosarcoma, Neur				•••••			•••••			
Neuronibrosarconia, Neur	onbroma, or o	0/50 (0%)	ingriant or NOS)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Sarcoma										
		3/50 (6%)				0/50 (0%)				
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Schwannoma Benign										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Schwannoma Malignant										
Occupation of the second	T-1-1	0/50 (0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	Maran 00/	OD 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

**Page:** 62

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Skin: Squamous Cell Carcine	oma							
•		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcine or Carcinoma	oma, Basal Cell (	Carcinoma, Basosquamo	us Tumor (malignan	t or NOS),				
		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Papillo		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma or Papilloma					0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma, Papilloma, S	Squamous Cell Carcinoma 5/50 (10%)	a or Keratoacanthon	na		0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma, Papilloma, o	or Keratoacanthoma 5/50 (10%)				0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: F 344/N

**Toxicology Data Management System** 

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Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE

Vehicle: METHYLCELLULOSE

			Male	Female				
#Skin: Trichoepithelioma								
•		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%)		05.00/		0/50 (0%)		05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)		05.00/		0/50 (0%)		05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma		•••••						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male		Female				
#Stomach, Glandular: Sarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Testes: Adenoma									
		35/50 (70%)							
Overall Incidence	Total	35/50 (70%)	Mean 70%	SD 0%					
*Testes: Hemangioma									
Overall Insidence	Tatal	0/50 (0%)	Mann 00/	CD 00/					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%					
*Thymus: Thymoma Benign		0/44 (0%)				0/48 (0%)			
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Malignant									
		0/44 (0%)				0/48 (0%)			
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma NOS									
		0/44 (0%)				0/48 (0%)			
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

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Report Date: 06/05/2013

SD 0%

Mean 0%

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female	
*Thymus: Thymoma: Benign, Maligna	nt, NOS	0/44 (0%)				0/48 (0%)		
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
'Thyroid Gland: C-Cell: Adenoma								
		6/46 (13%)				4/42 (10%)		
Overall Incidence	Total	6/46 (13.04%)	Mean 13.04%	SD 0%	Total	4/42 (9.52%)	Mean 9.52%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		0/46 (0%)				3/42 (7%)		
Overall Incidence	Total	0/46 (0%)	Mean 0%	SD 0%	Total	3/42 (7.14%)	Mean 7.14%	SD 0%
Thyroid Gland: C-Cell: Carcinoma or Adenoma		6/46 (13%)				7/42 (17%)		
Overall Incidence	Total	6/46 (13.04%)	Mean 13.04%	SD 0%	Total	7/42 (16.67%)	Mean 16.67%	SD 0%
Thyroid Gland: Follicular Cel Adenoma	l:						•••••	
		0/46 (0%)				0/42 (0%)		
Overall Incidence	Total	0/46 (0%)	Mean 0%	SD 0%	Total	0/42 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cel Carcinoma	l:	0/46 (09/)				0/42 (09/)		
		0/46 (0%)				0/42 (0%)		

SD 0%

0/42 (0%)

Total

Total

0/46 (0%)

Mean 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male		Female						
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma											
Overall Incidence	Total	0/46 (0%) 0/46 (0%)	Mean 0%	SD 0%	Total	0/42 (0%) 0/42 (0%)	Mean 0%	SD 0%			
#Tongue: Squamous Cell Carcinoma	 I										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Tongue: Squamous Cell Carcinoma	or Papilloma	a Squamous 0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Tongue: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Tooth: Adamantinoma Malignant						(00)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Urinary Bladder: Carcinoma		0/50 (00)				0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

## **Toxicology Data Management System**

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female			
*Urinary Bladder: Carcinoma or Papilloma									
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 00/	Total	0/50 (0%)	Moon 00/	SD 0%	
Overall incidence	Total	0/50 (0%)	wiean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	טע עצ 👊	
*Urinary Bladder: Hemangiosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Papilloma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Adenoma						0/50 (004)			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Carcinoma									
						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Leiomyosarcoma									
						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

# **Toxicology Data Management System**

Contract/Lab: All Laboratories Tumor Incidence fo

Contract/Lab: All Laboratorie
Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

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	Male			Female				
#Uterus: Polyp Stromal								
Overall Incidence		Total	17/50 (34%) 17/50 (34%)	Mean 34%	SD 0%			
#Uterus: Sarcoma								
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Sarcoma Stromal								
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Sarcoma Stromal or Polyp Stromal								
Overall Incidence		Total	17/50 (34%) 17/50 (34%)		SD 0%			
#Uterus: Schwannoma Malignant								
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Vagina: Polyp								
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Ma

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			Female			
#Vagina: Sarcoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Vagina:									
Schwannoma Malignant						- ()			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Adenoma			•••••						
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma or Adenoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied